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| APPLICATION NO.         | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|-------------|-----------------------|---------------------|------------------|
| 10/589,946              | 06/11/2007  | Jens Egebjerg Nielsen | P69516US1           | 2115             |
| 136                     | 7590        | 09/20/2010            | EXAMINER            |                  |
| JACOBSON HOLMAN PLLC    |             |                       | WILSON, LARRY ROSS  |                  |
| 400 SEVENTH STREET N.W. |             |                       |                     |                  |
| SUITE 600               |             |                       | ART UNIT            | PAPER NUMBER     |
| WASHINGTON, DC 20004    |             |                       | 3767                |                  |
|                         |             |                       | MAIL DATE           | DELIVERY MODE    |
|                         |             |                       | 09/20/2010          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/589,946             | NIELSEN ET AL.      |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | LARRY R. WILSON        | 3767                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 09 August 2010.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 32-42 is/are pending in the application.  
 4a) Of the above claim(s) 42 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 32-41 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 18 August 2006 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 9, 2010 has been entered.

### ***Election/Restrictions***

2. Newly submitted claim 42 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 42 is directed to a method of manufacturing that was not previously presented.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 42 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 32-41 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,755,173 to April A. Konopka et al. (Konopka).

In regards to claim 32, Konopka discloses a septum housing for an infusion device, comprising a tubular element (Fig. 10, #442) accommodating a septum (Fig. 11, #450), the septum being pierceable by a needle (Fig. 11, #426) and being radially compressed in the septum housing to provide a fluid-tight seal between the septum and the septum housing (col. 8, lines 18-20).

In regards to claims 33-36, Konopka discloses the septum housing according to claim 32, and further discloses:

Claim 33: at least one end of the tubular element provides a substantially partial enclosure over one surface of the septum (Fig. 11, #442 – shows opening to allow needle insertion through septum);

Claim 34: one end of the tubular element is open and leaves the surface of the septum exposed (Fig. 11, #450 – surface facing 444);

Claim 35: further comprising an integrally formed cannula bushing (lower surface of Fig. 11, #68 and upper surface of support ledge #48 by compression force inherently forms a bushing – similar notched structure supports septum 450 and forms cannula bushing);

Claim 36: the septum is fixed to inner surfaces of the septum housing by friction (col. 8, lines 32-34 – a component is sized larger than the holder to retain it inherently forms a friction fit).

In regards to claim 37, Konopka discloses an infusion device comprising a septum housing (Fig. 11, #442) that includes a tubular element (Fig. 10, #442) accommodating a septum (Fig. 11, #450), the septum being pierceable by a needle (Fig. 11, #426) and being radially compressed in the septum housing to provide a fluid-tight seal between the septum and the septum housing (col. 8, lines 18-20), and a base element (Fig. 11, #440) that includes a mounting surface (Fig. 11, #432), a distal end of the septum housing that faces away from a surface on which the infusion device is mounted constituting a part of an outer distal surface of the infusion device (Fig. 11, #442 – has an outer surface that is in direct opposition to the surface 432 mounted to the skin of the patient).

In regards to claims 38-41, Konopka discloses the infusion device according to claim 37, and further discloses:

Claim 38: one end of the tubular element provides a substantially partial enclosure over one surface of the septum , the end of the tubular element constituting a distal end of the septum housing (Fig. 11, #442 – shows opening to allow needle insertion through septum);

Claim 39: the septum housing is fixed to the base element by welding (col. 9, lines 43-46);

Claim 40: the welding is ultrasonic welding (col. 9, lines 43-46);

Claim 41: the septum housing is fixed to the base element by a snap-lock (col. 9, lines 43-46).

***Response to Amendment***

5. The amendment adding new claims 32-42, and the cancellation of claims 14-31, in the response filed on 9 August 2010 is acknowledged.

***Response to Arguments***

6. Applicant's arguments filed 9 August 2010 have been fully considered but they are not persuasive.

7. Applicant's argument that Konopka's structural features are different from applicant's claimed septum housing because applicant's septum is pre-mounted in the septum housing (Remarks pg. 6) are not persuasive because the claims are apparatus claims, they are not method of making claims that convey an order of manufacturing steps. Since Konopka discloses each structural element of the apparatus, claims 32-41 the claims are anticipated.

8. Applicant's argument that Konopka does not anticipate applicant's claimed invention because it lacks the limitation that one end of the septum housing constitutes a part of an outer distal surface of the infusion device (Remarks pg. 7) are not persuasive. Konopka elements 440 are septum housings in that they support and retain the septum in place, in accordance with the meaning of "housing", additionally, as shown above, element 442 forms a housing because it retains, supports, and partially covers the septum additionally it has an outer surface, as explained above, that faces in direct opposition to the adhesive surface 432 disposed against the patient's skin.

***Conclusion***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LARRY R. WILSON whose telephone number is (571)270-5899. The examiner can normally be reached on Monday-Thursday 7:00 AM - 5:30 PM (EST).
10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LARRY R WILSON/  
Examiner, Art Unit 3767

/Bhisma Mehta/  
Examiner, Art Unit 3767